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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193
23448	7590	04/05/2004	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709				WINKLER, ULRIKE
ART UNIT		PAPER NUMBER		
		1648		

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/684,026	DEVICO ET AL.
	Examiner	Art Unit
	Ulrike Winkler	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,6-11,13-16,24,34-57,60-65 and 73 is/are pending in the application.
- 4a) Of the above claim(s) 34-57 and 60-65 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,6-11,13-16,24 and 73 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/30/2003.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

The Amendment filed December 30, 2003 in response to the Office Action of October 14, 2003 is acknowledged and has been entered. Claims 34-57 and 60-65 are drawn to non-elected subject matter. Claims 1-3, 6-11, 13-16, 24 and 73 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Oath/Declaration

The office acknowledges the receipt of the oath and declaration submitted with the response on December 30, 2003. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Double Patenting

The rejection of claims 1-3, 6-8, 10, 11, 24 and 73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,518,723 in view of Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999) is **maintained** for reasons of record.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions

of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). In making the instant double patenting rejection the specification of the DeVico '723 was evaluated to determine if the term "covalently bonded" has a special meaning. Specifically, the specification was consulted to determine if the term "covalently bonded" would exclude the formation of a single chain molecule. Because the specification in DeVico '723 did not define "covalently bonded" to exclude a single chain molecule the term was given its plain meaning in the art; which is a chemical bond, formed between atoms by the sharing of electrons. To establish the plain meaning in the art the Examiner cited Webster's dictionary, the use of dictionaries is available in determining the meaning to any disputed term [Texas Digital Systems Inc. v. Telegenix Inc; 64 USPQ2d 1812 (CA FC 2002)]. Therefore, the instant invention remains rejected under obviousness-type double patenting.

The rejection of claims 1-3, 6-8, 10, 11, 24 and 73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,454 in view of Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999) **is maintained** for reasons of record. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422

F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). In making the instant double patenting rejection the specification of the DeVico '454 was evaluated to determine if the term "covalently bonded" has a special meaning. Specifically, the specification was consulted to determine if the term "covalently bonded" would exclude the formation of a single chain molecule. Because the specification in DeVico '454 did not define "covalently bonded" to exclude a single chain molecule the term was given its plain meaning in the art; which is a chemical bond, formed between atoms by the sharing of electrons. To establish the plain meaning in the art the Examiner cited Webster's dictionary, the use of dictionaries is available in determining the meaning to any disputed term [Texas Digital Systems Inc. v. Telegenix Inc; 64 USPQ2d 1812 (CA FC 2002)]. Therefore, the instant invention remains rejected under obviousness-type double patenting.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3, 6-11, 13-16, 24 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999) and DeVico et al. (U.S. Pat. No. 5,843,454, see IDS) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but are not fully persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's argues that the

DeVico et al. reference does not show a single chain polypeptide “This crosslinking agent forms a complex that is not a single chain polypeptide wherein the spacer forms a peptide bond between the alpha-amino acid group of one protein an the terminal alpha carboxyl group of a protein” (see page 8 of response). The DeVico ‘454 reference does teach that the interaction between the virus coat protein and the virus receptor exposes cryptic epitopes that are not present within the viral coat protein or the CD4 receptor structures alone (see column 2, lines 31-54).

Applicant’s argues that the Chackerian et al. reference does not disclose a polypeptide that uses viral coat sequences and receptor sequences that have a “bonding affinity” for each other. It is important to point out that the specification does not specifically define “bonding affinity” therefore bonding affinity is given the broadest interpretation which includes everything ranging from low affinity/nonspecific binding to high affinity binding. Applicants argue that there is a need for a “natural attraction”, it is important to point out that the claims do not recite the limitation of “natural attraction”. Even if the term “natural attraction” were included in the claim the term is also not defined in the specification and if included in the claim would be given the plain meaning that would not exclude low affinity/nonspecific binding of molecules.

Applicant’s have not provide any evidence that the viral coat protein and receptor protein taught in the Chackerian et al. reference would not have “bonding affinity” if placed into the same test tube. The Chackerian et al. reference teaches chimeric L1-CCR5 proteins, L1 is the viral capsid protein from bovine papillomavirus type-1 and CCR5 is a cell surface receptor and a coreceptor for some HIV strains. The reference teaches that antibodies raised to L1-CCR5 were effective at blocking viral infection in M-tropic virus strain using a single cycle replication assay (p 2376, column 2, 1st paragraph). That conformation is an important aspect in these chimera is indicated

by the fact that denatured L1-CCR5 chimeras did not induce antibody formation to CCR5, only in the context of the folded complex are antibody against the receptor produced. Intramolecular forces define the tertiary structure of the molecule; the reference clearly indicates that the tertiary structure is important for the production of antibodies that block viral infectivity.

Applicants are demanding the examiner to provide an affidavit supporting the statement “upon covalent bonding the two molecules any bonding and attractions the may have will then be termed intramolecular because once covalently bonded the complex become a single molecule”. An affidavit is not needed as Applicant’s could easily have consulted a Physical Organic Chemistry Dictionary for clarification of standard art recognized definitions (see IUPAC glossary terms I and M attached to the instant office action). Intermolecular is descriptive of any process that involves a transfer (of atoms, groups, electrons, etc.) or interactions between two or more molecular entities. Intramolecular is descriptive of any process that involves a transfer (of atoms, groups, electrons, etc.) or interactions between different parts of the same molecular entity. A molecular entity is any constitutionally or isotopically distinct atom, molecule, ion, ion pair, radical, radical ion, complex, conformer etc., identifiable as a separately distinguishable entity. Figure 4 of the DeVico et al. reference shows in lane 1 the molecular entity comprising gp120, lane 2 shows the molecular entity comprising CD4 and lane 3 shows the molecular entity comprising the gp120-CD4 complex. The complex is a single molecular entity in which the individual parts are no longer separable. Given these standard IUPAC definitions the DeVico et al. crosslinked complex comprises a molecular entity that is not separately distinguishable, therefore any forces that are experienced by the complex will be considered intramolecular.

The declaration under 37 CFR 1.132 filed by Dr. Anthony L. Devico is insufficient to overcome the rejection of claims 1-3, 6-11, 13-16, 24 and 73 based upon 35 USC 103 rejection as set forth in the last Office action because: The declaration compares the Balgp120/sCD4 complex with the full length single chain chimeras (FLSC). The declaration is not commensurate with the full scope the claims. The claims can include chimeras that are less than full length and that include other viral proteins from SIV, FIV and FeLV. Applicant's declaration is directed to unexpected results achieved using the FLSC chimeras when compared to the complexes using a crosslinker set out in the patent. The data provided in the declaration does not show that all epitopes are occluded by the crosslinking procedure see the result using the 2G12 antibody. Therefore, Applicant's showing of unexpected results is limited to the specific structures shown in the declaration and cannot be extrapolated to other single chain complexes or complexes using less than full-length structure. Claims limited to the FLSC chimera structure of HIV/CD4 would be allowable.

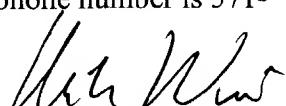
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please the fax phone number is 571-273-0912.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER
4/2/04